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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/565,717	01/23/2006	Boon P. Chew	46306646104	7940

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EXAMINER	
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ART UNIT	PAPER NUMBER
1651	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/565,717	CHEW ET AL.	
	Examiner	Art Unit	
	Kade Ariani	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-25 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-25 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The preliminary amendment filed on January 23, 2006, has been received and entered.

Claims 26 and 27 have been canceled.

Claims 1-25 are pending in this application and were examined on their merits.

Double Patenting Rejections

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Omum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory

double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-19 and 21-25 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 10-17 of Chew et al. US application No.10, 764, 215. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 10-17 of Chew et al. are drawn to a method of administering a composition to a subject comprising an effective amount of astaxanthin, a method of enhancing cell-mediated immune response, and daily administration of 0.001mg to 10 mg astaxanthin.

It would have been obvious to one skilled in the art at the time the invention was made to use the claimed method disclosed by Chew et al. to orally administer a therapeutically effective dose of astaxanthin to the subject and to reduce oxidative DNA damage in the immune cells of a subject.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-25 are rejected less than 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention nor was the claimed subject matter described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicant alleges that the instant method is a "method of preventing" and as the term "preventing" and "prevents" are absolute terms, the claims cannot be considered enabled for a "method of preventing". To enable a "preventing method" applicant would need to demonstrate to the skilled artisan that the method would prevent any and all cases and causes of the claimed oxidative damage in a humans immune cells and the specification has no such showing.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 3 and 22 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The phrase "no more than about " in claim 3 is indefinite because it is not exactly clear what percentage of free astaxanthin is encompassed by the phrase.

The recitation "the immune cells are cells" in claim 22 is indefinite because it is not clear what cells are encompassed by the recitation.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 4-8, 16-21, and 23-25 are rejected under 35 U.S.C. 102(a) as being anticipated by Guerin et al. (TRENDS in Biotechnology, May 2003, Vol. 21, No. 5 p.210-216).

Claims are 1, 2, 4-8, 16-21, and 23-25 are drawn to a method of reducing oxidative DNA damage comprising orally administering a therapeutically effective dose of a natural astaxanthin extract to a subject, the natural astaxanthin extract comprises

predominantly mono- and di-ester forms of astaxanthin, other carotenoids, natural astaxanthin extract is derived from *Haematococcus pluvialis*, the extract is greater than 95% (3S, 3'S) astaxanthin, the oxidative DNA damage comprises oxidative DNA damage in immune cells, the therapeutically effective dose is about 2 mg per day; about 4 mg per day, or about 8 mg per day.

Guerin et al. discloses a method of reducing oxidative DNA damage comprising orally administering a therapeutically effective dose of a natural astaxanthin extract (derived from *Haematococcus pluvialis* to a subject (see abstract and introduction p.210, column 2, last paragraph) the natural extract comprises predominantly mono- and diester forms of astaxanthin (p. 210, column 1, last paragraph), other carotenoids comprise β-carotene, canthaxanthin and lutein (p.211, figure 1.), each subject consumed daily 3.85 mg of astaxanthin and improvement in 85% of the health conditions (p. 214, column 1, lines 5-6 and Table 1.), the extract is greater than 95% (3S, 3'S) astaxanthin (p.210, column 2, lines 3-4) the oxidative DNA damage comprises oxidative DNA damage in immune cells (p.213, column 2, lines second paragraph), dried product can be directly encapsulated (powder, capsule or tablet) or the astaxanthin extracted can be included in nutraceutical (food or beverage) formulations (p.271, column 2, lines 33-35).

Guerin et al. therefore clearly anticipates the claimed invention.

Claims 1, 2, 4-8, 10, 11, 13-21 and 23-25 are rejected under 35 U.S.C. 102(b) as being anticipated by Lorenz (US Patent No. 6,433,025).

Lorenz discloses a method of reducing oxidative DNA damage comprising orally administering a therapeutically effective dose of a natural astaxanthin extract o a subject (see abstract and column 2, lines 5-7 also column 3, lines 43-46) astaxanthin is derived from *Haematococcus pluvialis* or from *Phaffia rhodozyma* (column 5 lines 48-58), the natural extract comprises predominantly mono- and di-ester forms of astaxanthin and the extract is greater than 95% (3S, 3'S) astaxanthin (column 6, lines 19- 21), other carotenoids comprise β-carotene, canthaxanthin and lutein (column 6, lines 27-28), is administered to the subject in combination with at least one additional biologically active compound (other carotenoids) (column 9, lines 39-41), natural astaxanthin extract dissolved in oil, aqueous medium, processed into dry matter and added to foods or beverages (column 10, lines 56-63), the natural astaxanthin mixed with oleic acid (safflower oil) and an adult female consumed 2 mg (1 mg per soft gel capsule) of astaxanthin per day (column 11, Examples 1 & 2, lines 29-61) the oxidative DNA damage comprises oxidative DNA damage in immune cells, astaxanthin supplementation increases the number of T and B lymphocytes, monocytes and can directly affect the immune responses to foreign antigens (column 8, lines 66-67 and column 9, lines 1-42). Lorenz therefore clearly anticipated the claimed invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lorenz (US Patent No. 6,433,025) in view of Valderrama et al. (J. Chem. Eng. Data, May 2003, Vol. 84 p.827-830).

As mentioned immediately above Lorenz teaches the limitations of claims 1, 2, 4-8, 10, 11, 13-21 and 23-25. Lorenz does not teach the claimed percentages of free, mono-, and diesters of astaxanthin, isomers of astaxanthin, and astaxanthin extract is produced by supercritical carbon dioxide extraction. However, Valderrama et al. teaches extraction of astaxanthin from microalgae *Haematococcus pluvialis* with supercritical carbon dioxide (see abstract and p.828, Figure 1.).

Moreover, at the time the invention was made optical (3S, 3'S) and geometrical (*E*, 9*Z*, and 13*Z*) isomers of the astaxanthin were all very well known in the art, also it was well known that composition of mono- and diesters of astaxanthin in the extract is dependent on the age of the culture and also the method of cultivation.

Therefore, it would have been obvious to one of the ordinary to extract astaxanthin from *Haematococcus pluvialis* using Valderrama et al.; because at the time the invention was made astaxanthin was being extracted from its natural source by supercritical carbon dioxide extraction method. One would have been motivated to use this method of extraction with a reasonable expectation of success, since at the time the invention was made supercritical carbon dioxide was found to be selective in the

separation of desired compounds without leaving toxic residues in the extracts and without the risk of thermal degradation of the processed products, as well as a more efficient and faster extraction than the conventional extraction methods.

Accordingly, the invention taken as whole is *prima facie* obvious in view of the patents, applications and prior art.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kade Ariani whose telephone number is (571) 272-6083. The examiner can normally be reached on 9:00 am to 5:30 pm EST Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic

Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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